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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/864,486	05/24/2001	Javier Mendez Diaz	976-9	2985
23869	7590	06/01/2004	EXAMINER	
HOFFMANN & BARON, LLP 6900 JERICHO TURNPIKE SYOSSET, NY 11791			LAMBERTSON, DAVID A	
			ART UNIT	PAPER NUMBER

1636

DATE MAILED: 06/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/864,486

Applicant(s)

DIAZ ET AL.

Examiner

David A. Lambertson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2004.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-26 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 6-26 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 6-9, 11 and 13-26, drawn to an isolated/recombinant DNA fragment comprising SEQ ID NO: 1 (including the combination of SEQ ID NO: 1 and SEQ ID NO: 2), a vector/construct comprising said DNA fragment, a host cell comprising said vector/construct, and a method of regulating heterologous gene expression using the promoter identified as SEQ ID NO: 1, classified in class 435, subclass 41.
- II. Claims 6-8, 10, 12-14 and 16-24, drawn to an isolated/recombinant DNA fragment comprising SEQ ID NO: 2 (including the combination of SEQ ID NO: 2 and SEQ ID NO: 1), a vector/construct comprising said DNA fragment, a host cell comprising said vector/construct, classified in class 536, subclass 24.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions Group I and Group II are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention Group I, which represents a promoter sequence (SEQ ID NO: 1), has separate utility such as its use with a separate terminator sequence (i.e., a terminator that is distinct from SEQ ID NO: 2), or as a DNA probe to identify promoter orthologues in related organisms. Similarly, invention Group II, which represents a terminator sequence (SEQ ID NO: 2), has separate utility such as its use with a

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separate promoter sequence (i.e., a promoter that is distinct from SEQ ID NO: 1), or as a DNA probe to identify terminator orthologues in related organisms. See MPEP § 806.05(d). It is noted that upon the election of Group I or II, the combination of sequences (SEQ ID NO: 1 and 2) must necessarily be searched in either case. However, this does not preclude the restriction of the individual sequences, which are broader in nature than the specific combination, and thus require a burdensome search.

Pursuant to 35 U.S.C. 121 and 37 C.F.R. 1.141, the sequences listed in claim 6, 8 and 13 are subject to restriction. The Commissioner has partially waived the requirements of 37 C.F.R. 1.141 and will permit a reasonable number of such sequences to be claimed in a single application. Under this policy, a single independent and distinct sequence will be examined in a single application. The sequences are considered to be unrelated since each sequence claimed is structurally and functionally independent and distinct for the following reasons: each sequence has a distinct chemical structure which confers a distinct biochemical function on the sequence (e.g., SEQ ID NO: 1 has a sequence/structure that provides a promoter function, whereas SEQ ID NO: 2 has a sequence/structure which confers a terminator function on the molecule). Furthermore, a search of more than one (1) of the sequences claimed presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed sequences. In view of the foregoing, one (1) sequence is considered to be a reasonable number of sequences for examination.

In further explanation, it is noted that a search of SEQ ID NO: 1 will not necessarily identify SEQ ID NO: 2, although a search of a molecule comprising SEQ ID NO: 1 will

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necessarily cover the combination of SEQ ID NO: 1 plus SEQ ID NO: 2. However, the combination, if it is found to be free of the art, does not necessarily indicate that SEQ ID NO: 2, outside of the combination, is free of the art. This is because SEQ ID NO: 2, as set forth above in the restriction, could be present in a molecule with a separate and distinct promoter from SEQ ID NO: 1. As a result, a simultaneous search of SEQ ID NO: 1 and SEQ ID NO: 2 as individual sequences would be necessary in the absence of a restriction, which presents an undue search burden to the Office.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Furthermore, especially in instances where the classifications are the same, the non-patent literature searches required for each of these inventions are not co-extensive, hence said searches would be burdensome. Therefore restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

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application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (571) 272-0771. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David A. Lambertson, Ph.D.
AU 1636


JAMES KETTER
PRIMARY EXAMINER